

SAFC®

Pharma & Biopharma Raw
Material Solutions

Millipore SIGMA

APIs tailored to your needs

The secret of our future-ready active pharmaceutical ingredients (APIs) lies in our past: With our long experience in production of high quality APIs, we have extensive knowledge and expertise of providing excellent regulatory documentation and support. And we know that regulatory requirements are challenging, and incomplete documentation can significantly delay the market launch of your products.

Consequently, our comprehensive portfolio of high-quality APIs is backed by extensive documentation to provide you with maximum product safety and compliance assurance – and to help you shorten your time to market.

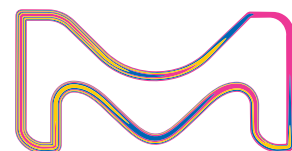
The highlights of our APIs at a glance:

- Life improving APIs, covering a wide range of applications from enteral and parenteral nutrition to oncology, from ophthalmic to plasmapheresis and dialysis, and more.
- All APIs are manufactured under GMP Guidelines, e.g. ICH Q7, FDA CGMP, etc.
- Regulatory e-submissions (e.g., US-DMF, CEP, ASMF) to support your drug product marketing authorization
- Compliant with pharmacopoeias worldwide to meet international quality standards
- Suitable for liquid, solid and semisolid formulations



Making it easy for you:

- Your trusted API partner
- Samples available for qualification
- Customized services upon request
- For more information, please contact your local sales representative



Emprove[®] APIs

With our active pharmaceutical ingredients under the Emprove[®] Program we provide dedicated regulatory support worldwide throughout the entire registration process backed by an excellent compliance track record.

- Manufactured under GMP Guidelines, e.g. ICH Q7, FDA CGMP, etc.
- Regulatory e-submissions (e.g., US-DMF, CEP, ASMF)
- Emprove[®] API Information Package included to speed up your qualification and risk assessment*

More information about the Emprove[®] Program can be found at sigmaaldrich.com/emprove

Folates

Benefit from more than 70 years of experience and a comprehensive portfolio of reduced folates for both pharmaceutical and nutritional applications.

Our Calcium Folate offerings:

- Calcium Folate crystalline (Leucovorin Calcium crystalline), (6R,S)-5-Formyltetrahydrofolic acid, Calcium Salt, suitable for solid formulations
- Calcium Folate amorphous (Leucovorin Calcium amorphous), (6R,S)-5-Formyltetrahydrofolic acid, Calcium Salt, which quickly dissolves and is advantageous during the production of liquid formulations or lyophilisates
- Our Calcium Folate fulfills specifications that are tighter than the requirements of the European- or United States Pharmacopoeia

Our Levomefolate Calcium (Metafolin[®] API) offering:

- Our Levomefolate Calcium offers a more bioavailable alternative to folic acid and comes with broad industry usage since its introduction in 2006
- It fulfills the specifications of the United States Pharmacopoeia (USP)

Our Calcium Levofolate Pentahydrate offering:

- The first company worldwide to produce Calcium Levofolate Pentahydrate (Levoleucovorin Calcium Pentahydrate), (6S)-5-Formyltetrahydrofolic acid, Calcium Salt in commercial quantities

As an industry leader for commercial production of reduced folates, we continue to evolve and innovate. Let's **exchange** how our folates could support your high-quality products!

*available only for Emprove[®] branded products

Our portfolio of APIs

Order No.	Product
EMPROVE® APIs	
100164	Boric acid cryst. EMPROVE® API Ph Eur, BP, NF
102465	Calcium chloride dihydrate EMPROVE® API Ph Eur, BP, ChP, JP, USP
500112	Cocarcboxylase chloride thiamine diphosphoric acid ester chloride EMPROVE® API
500111	Cocarcboxylase tetrahydrate (thiamine diphosphoric acid ester tetrahydrate) EMPROVE® API
102367	Magnesium chloride hexahydrate cryst. EMPROVE® API Ph Eur, BP, JPC, USP
106143	Meglumine, low in endotoxins EMPROVE® API Ph Eur, ChP, JP, USP
109828	di-Potassium hydrogen phosphate anhydrous, low in sodium EMPROVE® API Ph Eur, BP, USP
105040	Potassium iodide EMPROVE® API Ph Eur, BP, ChP, JP, USP
128204	Sodium acetate trihydrate EMPROVE® API Ph Eur, BP, JP, USP, FCC, E 262
106444	Sodium chloride EMPROVE® API Ph Eur, BP, JP, USP
106666	tri-Sodium citrate dihydrate EMPROVE® API Ph Eur, BP, JP, USP
108432	Urea cryst. EMPROVE® API Ph Eur, BP, USP
128220	Zinc chloride EMPROVE® API Ph Eur, BP, JP, USP

Order No.	Product
Folates	
CH2900010	Calcium folinate amorphous, Ph Eur / Leucovorin calcium amorphous, USP
CH2900011	Calcium folinate crystalline, Ph Eur / Leucovorin calcium crystalline, USP
CH2900018	Calcium levofolate pentahydrate, Ph Eur / Levoleucovorin calcium pentahydrate
CH2900056	Levomefolate calcium (Metafolin® API)
Other APIs	
ARK2015	Acepromazine Maleate, USP, BP
ARK2163	Benzyl Alcohol, NF, Ph Eur
ARK2055	Brompheniramine Maleate, USP, BP, Ph Eur
ARK2117	Butoconazole Nitrate Milled, USP
ARK2116	Butoconazole Nitrate Micronised, USP
ARK2091	Clomipramine Hydrochloride, USP, BP, Ph Eur
ARK2009	Doxylamine Succinate, USP, BP, Ph Eur
ARK2210	Ethanol Ph Eur, USP, ACS
ARK2046	Lofepamine Hydrochloride, BP, Ph Eur
ARK2086	Nortriptyline Hydrochloride, USP, BP, Ph Eur
ARK2062	Promethazine Hydrochloride, USP, BP, Ph Eur
ARK2148	Sodium Benzoate, Ph Eur
Under request	Calcitriol, European Pharmacopoeia (EP)
CH2900034	Zinc histidine dihydrate

Learn more about our high-quality folates:

[SigmaAldrich.com/folates](https://sigmaaldrich.com/folates)

We provide information and advice to our customers on application technologies and regulatory matters to the best of our knowledge and ability, but without obligation or liability. Existing laws and regulations are to be observed in all cases by our customers. This also applies in respect to any rights of third parties. Our information and advice do not relieve our customers of their own responsibility for checking the suitability of our products for the envisaged purpose.

For additional information, please visit [SigmaAldrich.com/emprove](https://sigmaaldrich.com/emprove)

To place an order or receive technical assistance, please visit [SigmaAldrich.com/contactAF](https://sigmaaldrich.com/contactAF)

MilliporeSigma, the Vibrant M, Emprove and SAFC are trademarks of Merck KGaA, Darmstadt, Germany or its affiliates. All other trademarks are the property of their respective owners. Detailed information on trademarks is available via publicly accessible resources.
©2024 Merck KGaA, Darmstadt, Germany and/or its affiliates. All Rights Reserved.

Lit. No. MS_FL11997EN

